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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,613	08/04/2000	Holly Hogrefe	4121.0116-07	6689

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EXAMINER	
WILDER, CYNTHIA B	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 02/14/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/631,613	Hogrefe, et al.
Examiner	**Art Unit**
Cynthia B Wilder	1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 3, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *40-44 and 69-74* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *40-44 and 69-74* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

FINAL ACTION

1. Applicant 's request for reconsideration in Paper 13 is acknowledged. Claims 40-44 and 69-74 are pending. All of the arguments have been thoroughly reviewed and considered but they are not found persuasive for the reasons that follow. Any rejection not reiterated in this action have been withdrawn as being obviated by the amendment of the claims.

This Action is made final.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejections

3. The claim rejections under 35 U.S.C. 112 second paragraph are withdrawn in view of Applicant's arguments. The prior art rejection under 35 U.S.C. 102 (b) directed to claims 40 and 42-44 as being anticipated by Barnes is withdrawn in view of Applicant's arguments. The prior art rejection under 35 U.S.C. 102(b) directed to claims 40-44 as being anticipated by Nielson is withdrawn in view of Applicant's arguments. The prior art rejection under 35 U.S.C. 102(a) directed to claims 71 and 73 as being anticipated by Lasken et al. is maintained. The double patenting rejection is maintained.

Claim Rejections - 35 U.S.C. § 102

4. Claims 71 and 73 are rejected under 35 U.S.C. 102(a) as being anticipated by Lasken et al. (*JBC, vol. 271, pp 17692-17696, 1996*) . Regarding claims 71 and 73, Lasken et al. teach a method of enhancing a nucleic acid polymerase reaction comprising performing the reaction in

the presence of a dUTPase activity wherein the dUTPase activity comprises an archael dUTPase (page 17694, col. 2, lines 3-10 and page 17696, col. 1, lines 19--21 and 28-31). Therefore, Lasken et al. meet the limitations of claims 71 and 73 of the instant invention.

5. Applicant traverses the rejection on the following grounds: Applicant states that Lasken does not teach a method of enhancing polymerase activity in the presence of a dUTPase activity. Applicant states that the portions of Lasken cited by the Examiner describe the inhibition of polymerase activity by uracil containing DNA, the incorporation of dUTP into polymerization by an exo-Vent polymerase, or the incorporation of dUMP (not dUTP) into polymerization when dTTP and dUTP are absent. Applicant states that nowhere does Lasken describe polymerase enhancement by the presence of dUTPase activity. Applicant concludes that the Examiner has failed to show where Lasken teaches a method of enhancing polymerase activity in the presence of a dUTPase activity and accordingly request the rejection be withdrawn.

6. The arguments filed in Paper No. 13 have been thoroughly reviewed and considered but are not found persuasive for the reasons that follows: The courts have established that during patent examination the pending claims must be interpreted as broadly as their terms reasonably allow *(In re Zeltz, 893 F. 2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed Cir, 1989)*. In this case the claims as broadly written do not teach a method of enhancing polymerase activity in the presence of a dUTPase activity. The claims as broadly written only requires dUTPase activity in the PCR reaction. There is no indication from the claim that polymerase enhancement must occur. The reference of Lasken meets the limitation of the claimed invention because Lasken et al. teach wherein dUTP is

added to a polymerase reaction which resulted in a longer product (page 17694, col. 2). The fact that dUTP was utilized by Vent DNA polymerase in the polymerase reaction is irrelevant to the instant invention because the claims as written do not exclude the use of a Vent DNA polymerase in the reaction. To reiterate, the reference only requires dUTP to be present in a polymerase reaction. Applicant has not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections. Accordingly, the rejection directed to claims 71 and 73 are maintained.

Double Patenting

7. Once again, claims 40-44 and 69-74 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,183,997 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of patent '997 discloses an obvious species of the instant invention. Claims 1-29 of patent '997 teach a composition comprising at least one component possessing nucleic acid polymerase enhancing activity selected from the group consisting of : an isolated or purified naturally occurring polymerase enhancing protein obtained from an archeabacteria source; a wholly or partially synthetic protein having the same amino acid sequence as said naturally-occurring protein or analogs thereof possessing polymerase enhancing activity. The claims further

teach wherein the composition comprises at least one subunit having a molecular weight of approximately 45 kD.

The claims of patent '997 do not expressly teach wherein the composition comprising the polymerase enhancing activity is utilized in a polymerization reaction as claimed in the instant invention , however, one of ordinary skill in the art would recognize that the composition is capable of use in methods of enhancing a nucleic acid polymerase reaction. The claims of the instant invention and patent '997 are not patentably distinct and only differ slightly in scope.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's Patent Analyst, Monica Graves at (703) 305-3002 or Group's receptionist at (703) 308-0196.

Cynthia B. Wilder, Ph.D.

February 11, 2003

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

2/12/03